

CLAIMS

What is claimed is:

1. A bypass graft comprising a tubular portion having an internal tubular diameter and a first end and a second end, said tubular portion having a central axis; a flared portion having an adjoining end, wherein said adjoining end of said flared portion is integrally formed on and is substantially concentric with said second end of said tubular portion, and a flared end, wherein said flared end has a flared end internal diameter, such that said internal flared end diameter is greater than said internal tubular diameter; whereby said flared portion comprises a circumferential skirt for surgical attachment of said graft to a patient's blood vessel.
2. The graft of claim 1, wherein said graft is monolithic.
3. The graft of claim 1, wherein said graft is made from a polymer selected from the group consisting of polyether urethanes, polycarbonate urethanes, polyester urethanes, silicone polyether urethanes, silicone polycarbonate urethanes, and PHMO polyurethanes.
4. The graft of claim 3, wherein said polyether urethane comprises a polyether urethane-urea.
5. The graft of claim 4, wherein said polyether urethane-urea further comprising an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.
6. The graft of claim 4, wherein said polyether urethane-urea is end-capped with dibutylamine.
7. The graft of claim 1, wherein said graft comprises:
an inner first micro-porous layer of polyether urethane-urea comprising polymeric solids comprising about 1% by weight of an additive formed by condensing MDI, polydimethylsiloxane, and 1,4-butanediol;
a second nonporous layer of polyether urethane-urea comprising polymeric solids comprising about 4.5% by weight of said additive; and
a third porous layer of a polyether urethane-urea comprising polymeric solids comprising about 3.5% of said additive.
8. The graft of claim 7, wherein said first layer is contiguous with said second layer.
9. The graft of claim 7, wherein said second layer is contiguous with said third layer.

10. The graft of claim 7, wherein said first layer contains pores having an average diameter of less about 38 microns.

11. The graft of claim 7, wherein said third layer contains pores having an average diameter less than about 38 microns.

12. The graft of claim 1, wherein said flared end has a flared end central axis, which is at an oblique angle to said central axis of said tubular portion.

13. The graft of claim 12, wherein said graft is monolithic.

14. The graft of claim 12, wherein said graft is made a polyether urethane-urea and said polyether urethane-urea further comprises an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.

15. The graft of claim 1, wherein said skirt member is oriented for attaching at an acute angle to said blood vessel.

16. The graft of claim 15, wherein said graft is monolithic.

17. The graft of claim 16, wherein said graft is made from a polyether urethane-urea and said polyether urethane-urea further comprises an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.

18. The graft of claim 1, wherein said flared end has a flared end central axis, which is parallel to said central axis of said tubular portion.

19. The graft of claim 18, wherein said graft is monolithic.

20. The graft of claim 18, wherein said graft is made from a polyether urethane-urea and said polyether urethane-urea further comprises an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.

21. The graft of claim 1 wherein said skirt member is elongated.

22. The graft of claim 21, wherein said graft is monolithic.

23. The graft of claim 21, wherein said graft is made from a polyether urethane-urea and said polyether urethane-urea further comprises an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.

24. The graft of claim 1, wherein said graft comprises reinforcing member wound around and substantially concentric with said tubular portion.

25. The graft of claim 24, wherein said graft is monolithic.

26. The graft of claim 25, wherein said graft is made from a polyether urethane-urea and said polyether urethane-urea further comprises an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.

27. The graft of claim 1, wherein said flared end is asymmetrically flared with respect to said central axis of said tubular portion, such that said skirt has a substantially elliptically-shaped circumference.

28. The graft of claim 27, wherein said graft is monolithic.

29. The graft of claim 27, wherein said graft is made from a polymer selected from the group consisting of polyether urethanes, polycarbonate urethanes, polyester urethanes, silicone polyether urethanes, silicone polycarbonate urethanes, and PHMO polyurethanes.

30. The graft of claim 29, wherein said polyurethane comprises a polyether urethane-urea.

31. The graft of claim 29, wherein said polyether urethane-urea further comprising an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.

32. The graft of claim 30, wherein said polyether urethane-urea is end-capped with dibutylamine.

33. The graft of claim 27, wherein said graft comprises:

an inner first micro-porous layer of polyether urethane-urea comprising polymeric solids comprising about 1% by weight of an additive formed by condensing NMI, polydimethylsiloxane, and 1,4-butanediol;

a second nonporous layer of polyether urethane-urea comprising polymeric solids comprising about 4.5% by weight of said additive; and

a third porous layer of a polyether urethane-urea comprising polymeric solids comprising about 3.5% of said additive.

34. The graft of claim 33, wherein said first layer is contiguous with said second layer.

35. The graft of claim 33, wherein said second layer is contiguous with said third layer.

36. The graft of claim 33, wherein said first layer contains pores having an average diameter of less about 38 microns.

37. The graft of claim 33, wherein said third layer contains pores having an average diameter of less than about 38 microns.

5 38. A graft of claim 27, wherein said skirt comprises an opening for attaching said skirt at an acute angle to said blood vessel.

39. The graft of claim 27, wherein the flared end comprises an elliptically-shaped opening, which is oriented at an oblique angle to said central axis of said tubular portion.

40. The graft of claims 27, wherein said skirt member is elongated.

10 41. A method for manufacturing a bypass graft, comprising the steps of:
providing a mandrel having a tubular portion and a flared end bulb with a flared end central axis;

forming at least one layer of polyurethane over said mandrel;

drying said at least one layer of polyurethane, on said mandrel;

15 forming a skirt edge around said flared end bulb of said mandrel to form an opening at a predetermined angle to said flared end central axis;

forming a second edge around said tubular portion of the mandrel; and

removing said graft from said mandrel.

20 42. The method of claim 41, further comprising the steps of.

providing a first source of polyurethane comprising polymeric solids and sodium chloride particles, such that said sodium chloride particles are in an amount equal to about 1400% by weight of said polymeric solids;

applying a first layer of said source of polyurethane over said mandrel; and

leaching said sodium chloride particles from said first layer to form pores.

25 43. The method of claim 41, further comprising the steps of.

providing a third source of polyurethane comprising polymeric solids and sodium chloride particles, such that said sodium chloride particles are in an amount equal to about 600% by weight of said polymeric solids;

applying a third layer of said third source of polyurethane over said mandrel; and

30 leaching said sodium chloride particles from said third layer to form pores.

44. The method of claim 41, further comprising the steps of:

wrapping said graft with a reinforcing means; and
securing said reinforcing means by applying a polyurethane layer thereover.

45. The method of claim 41, wherein the step of forming at least one layer of polyurethane over said mandrel comprises drawing said mandrel through said source of polyurethane.

5 46. The method of claim 45, wherein the step of forming at least one layer of polyurethane comprises repeatedly drawing said mandrel through said source of polyurethane.

47. The method of claim 41, further comprising the step of forming said skirt edge and controlling a length of said graft by applying a mask to said mandrel to limit exposure of the surface of said mandrel to said source of polyurethane.

10 48. The method of claim 47, further comprising the step of cutting the flared end of said graft subsequent to removal of said mandrel to impart an asymmetrical opening on said graft.

49. The method of claim 41, wherein the step of forming at least one layer of polyurethane over said mandrel comprises dipping said mandrel into said source of polyurethane.

15 50. The method of claim 49, wherein the step of forming at least one layer of polyurethane comprises repeatedly dipping said mandrel through said source of polyurethane.

51. The method of claim 49, further comprising the step of controlling a length of said graft by limiting a depth to which said mandrel is dipped into said source of polyurethane.

20 52. The method of claim 50, further comprising the step of forming said skirt edge and controlling a length of said graft by applying a mask to said mandrel to limit exposure of the surface of said mandrel to said source of polyurethane.

53. The method of claim 49, further comprising the step of cutting the flared end of said graft subsequent to removal of said mandrel to impart an asymmetrical opening on said graft.

54. The method of claim 41, wherein the step of forming at least one layer of polyurethane over said mandrel comprises spraying said source of polyurethane onto said mandrel.

25 55. The method of claim 54, wherein the step of forming at least one layer of polyurethane comprises repeatedly spraying said source of polyurethane onto said mandrel.

56. The method of claim 54, further comprising the step of forming said skirt edge and controlling a length of said graft by applying a mask to said mandrel to limit exposure of the surface of said mandrel to said source of polyurethane.

57. The method of claim 54, further comprising the step of forming said skirt edge and controlling a length of said graft by directing a sprayed stream of said source of polyurethane onto a selected portion of said mandrel.

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